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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/285,429	04/02/99	SHIRLEY	5764.5

HM22/0512

CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
P O BOX 8097
EMERYVILLE CA 94620-8097

EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1653	9

DATE MAILED: 05/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/285,429	Applicant(s) Shirley
	Examiner F. T. Moezie	Group Art Unit 1653

☒ Responsive to communication(s) filed on *Apr 2, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *thirty* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 13-14, drawn to a composition comprising a pharmaceutically active agent, classified in various class and subclasses depending on the elected pharmaceutically active, agent.

II. Claims 11 and 12, drawn to a composition comprising IGF-I or a biologically active variants thereof, classified in class 530, subclass 350+.

III. Claims 15-18, drawn to a method for the treatment of a disease or condition, comprising administering by injection, a pharmaceutical composition comprising a pharmaceutically active agent, classified in various class and subclasses depending on the structure of the pharmaceutically active agent in the composition.

IV. Claims 15-18, drawn to a method for prevention of a disease or condition, comprising administering by injection, a pharmaceutical composition comprising a pharmaceutically active agent, classified in various class and subclasses depending on the structure of the pharmaceutically active agent in the composition.

V. Claims 15-18, drawn to a method for diagnosis of a disease or condition, comprising administering by injection, a pharmaceutical composition comprising a

pharmaceutically active agent, classified in class 424, subclasses 9.1+, for example.

VI. Claims 19-20, drawn to a method for the treatment of a disease or condition, comprising administering by injection a composition comprising IGF-I or a biologically active variant thereof as active agent, classified in class 514, subclass 12+, for example.

VII. Claims 19-20, drawn to a method for the prevention of a disease or condition comprising administering by injection a composition comprising IGF-I or a biologically active variant thereof, classified in class 514, subclass 12+, for example.

VIII. Claims 19-20, drawn to a method for the diagnosis of a disease or condition comprising administering by injection a composition comprising IGF-I or a biologically active variant thereof, classified in classified in class 424, subclass 9.1+, for example.

The inventions are distinct, each from the other because of the following reasons: Inventions I to II and III to VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as use thereof in a pill or for oral administration.

Inventions III, IV or V and VI, VII or VIII are distinct methods of use. The inventions are distinct because they use structurally different pharmaceutically active agents in the methods, have different method objectives, modes of operation, different hosts, dosages and follow distinct method steps. Hence, the searches are not co-extensive. It would be an undue burden to examine all of the methods in one application.

Inventions I or II are also distinct one from the other. Inventions are distinct because each composition comprises a structurally distinct pharmaceutically active agent. Hence, each composition would require a separate search and consideration of patentability. Because the pharmaceutical agents used in the compositions have varying structure, a search for all of the agents in one application would require undue burden of search on the examiner.

Because these inventions are distinct for the reasons given above and the search required for any one of the Groups is not required for any other Group of invention, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

SPECIES ELECTION

This application contains claims directed to the following patentably distinct species of the claimed invention: a) species of a pharmaceutically active agent and b) species of IGF-I variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement along with the election of an Ultimate Specie for the invention, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined along with the election of an ULTIMATE SPECIE even though the requirement be traversed (37 CFR 1.143). An ULTIMATE SPECIE is a compound wherein all of the variables parameters are accounted for.

NOTE: In the event applicant elects claims drawn to one of the methods of use and the method is found to be allowable, Examiner will consider a rejoinder of the composition claims which are commensurate in scope with the allowable method of use claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. T. Moezie whose telephone number is (703) 305-4508 or Mr. LOW (SPE) at 308-2923. FAX: (703) 305-4508

F. T. Moezie

F. T. MOEZIE, PH.D.
PRIMARY EXAMINER
ART UNIT 1653